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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/665,452

09/19/2003

Lisa Tam

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EXAMINER

JACKSON, BRANDON LEE

ART UNIT

PAPER NUMBER

3772

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

04/17/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/665,452

Applicant(s)

TAM ET AL.

Examiner

Brandon Jackson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03/25/2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 February 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

This action is in response to arguments/amendments filed on 3/25/2007.

Currently claims 1-38 are pending in the present application.

Response to Arguments

Applicant's arguments filed 03/25/2007 have been fully considered but they are not persuasive. Applicant argues the friction-imparting agent of Harmon does not cling to the walls of the vagina proximate a transition zone between the vagina's introitus and its rugated internal vaginal tissue. However, Harmon discloses a friction-imparting agent clings to the walls of the vagina to stabilize the condom; the exact position of the friction-imparting agent relative to the vaginal walls is not a patentable issue. It would involve routine skill in the art to move the friction-imparting agent along the outer surface of the condom and to anchor it at both ends instead of just the distal end. Applicant argues the inserter and the package of Lash do not function the same as the claimed invention. However, the Lash inserter (37) holds the condom pouch in a collapsed position until it is within the vaginal cavity. The cling imparting elements would inherently be within the inserter if it were modifying the Harmon condom, because it has cling elements on the distal end. The package (68) of Lash would contain the inserter and cling elements in a collapsed position; otherwise the condom would not fit within the package. Applicant argues Harmon does not teach or suggest hydrophilic or polyurethane hydrophilic foam. However, Harmon teaches hydrocolloid which is hydrophilic (col. 4, lines 35-40). A foam is a solid with a dispersion of gas bubbles throughout; and a colloid is a substance is a substance with a dispersion of particles

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that can be gaseous. Also, Harmon teaches polyurethane (col. 4, lines 45-50).

Applicant argues the friction-imparting agents are not elliptical, triangular, or circular shaped and are 0.75 square inches, however this is a mere design consideration and does not patentably affect the device. Applicant has not set forth any arguments or evidence as to any critical reason for the shape and size of the cling elements; therefore any shape and size would suffice as long as the same function is accomplished.

Applicant argues the pleats taught by Feng cannot be used to modify the Lash/Harmon device because Feng teaches a male condom instead of a female condom. Male and female condoms are considered to be analogous art, therefore the teachings of Feng can be used to modify Lash/Harmon.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1- 24, and 27-29 rejected under 35 U.S.C. 103(a) as being unpatentable over Lash (U.S. Patent 4,867,176) in view of Harmon (U.S. Patent 5,137,032). Lash discloses a female condom (21) comprising a pouch (22) of resilient membranous material having an open end (24), a closed end (23), an outer surface (28), an inner surface (fig. 4), and a longitudinal axis (fig. 4). Further, the lash condom comprises an inserter (37) coupled to said pouch (22) for retaining a distal portion (23) and facilitating insertion of said female condom (21) into a vagina. The inserter (37) is attached to said pouch (22). The pouch (22) is slidably inserted in the inserter (37). The inserter (37) expands to cling to the walls of the vagina and hold the female condom (21) in position for usage. The inserter (37) is elastomeric as it compresses to enter the vagina, and then expands after insertion hold position with in the vagina (col.4, lines 23-28). Also, Lash discloses a packaged (fig. 16) female condom (21), wherein the condom and applicator are received within a cap-like receptacle or inserter. Lash fails to disclose hydrophilic cling elements attached to the outer surface of the female condom and adapted to anchor said pouch in or slightly beyond the vagina's introitus. Hydrophilic cling elements defined generally by a triangular or circular shape. As well as, the inserter being formed of the same material as the cling element and being dissolvable. However, Harmon teaches a plurality of hydrophilic (col. 4, line 30) friction-imparting agents or cling elements (20) disposed in a belt-like pattern. The friction-imparting agent (20) is defined generally by an elliptical shape and is water-soluble (col. 4, line 39). The segment that holds the hydrophilic friction-imparting agent (20) to the condom can be made materials including hydrophilic polyurethane (col. 4, lines 45-50). The

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friction-imparting agent (20) clings to the vaginal walls in order to stabilize the condom within the vagina (col. 2-3, lines 62-66, 1-3). Harmon teaches the use of water-soluble and dissolvable material, polyvinyl alcohol (col. 4, lines 35-40) for portions connected to the condom. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the female condom of Lash with the friction-imparting agents as taught by Harmon, and substitute the material of Lash for polyvinyl alcohol foam as taught by Harmon; because the friction-imparting agents of Harmon would give the female condom of Lash more stability and help to ensure minimal movement of the condom during intercourse. Moreover, the polyvinyl alcohol foam is meant to be used with contraceptive devices and would work equally as well with the inserter of Lash.

With respect to claim 8, Applicant has not asserted that the total surface area of the hydrophilic cling element of .75 square inches provides a particular advantage, solves a stated problem, or severs a purpose different from that of any hydrophilic frictional element connected to a condom, thus the .75 square inches lack criticality in its design. Therefore, one of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with friction-imparting agent of Harmon because they both perform the same function of frictionally clinging to the walls of the vagina for reason of immobilizing a condom.

Claims 25-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lash/Harmon as applied to claim 13 above, and further in view of Feng (U.S. Patent 6,170,484). Lash/Harmon disclose: see above rejection of claim 23. Also, Lash/Harmon

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disclose a plurality of longitudinal pleats (61) formed in the distal portion of the pouch (fig. 12) However, Lash/Harmon fail to disclose a plurality of pleats formed in the circumferential direction of the distal portion of the pouch. However, Feng teaches a plurality of longitudinal and horizontal pleats (fig. 6) on a female condom (101).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the condom of Lash/Harmon with the pleats as taught by Feng, because they allow for the easy application of the female condom.

Claims 33-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lash (U.S. Patent 4,867,176) in view of Harmon (U.S. Patent 5,137,032). Lash/Harmon substantially discloses the claimed invention; see rejections to claims 1, 18, and 23 above.

With respect to claims 33-35, Lash/Harmon fails to disclose the cling element is welded to the outer surface of the pouch. Claims 33-34 are apparatus claims and welding is a process of attaching the cling element to the pouch. Therefore, since the friction-imparting element (20) of Lash/Harmon is permanently attached to the pouch like the claimed invention the devices are structurally equivalent.

With respect to claims 36-38, Lash/Harmon fails to disclose the cling elements are 3 to 4 inches from the open end of the condom. However, Applicant fails to disclose a criticality of the cling elements being between 3 and 4 inches from the open end. The Lash/Harmon device would function equally as well with the cling elements being 3 to 4 inches from the open end of the condom, because it is a mere design consideration. It would have been obvious to one of ordinary skill in the art at the time of the invention to

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modify the Lash/Harmon device to have the cling elements 3 to 4 inches from the open end of the condom.

Allowable Subject Matter

Claims 30-32 are allowed because the prior art made of record does not teach or fairly suggest a method of packing a female condom wherein said female condom's lateral and longitudinal pleats are collapsed along the longitudinal axis into an inserter about the distal portion. The pouch of the female condoms is placed over a mandrel and air disposed between the pouch and mandrel is withdrawn and the pouch collapses about the mandrel. Then, where folding the female condom comprises rotating each of the longitudinal pleats clockwise or counter-clockwise and wherein the step of forming lateral pleats comprises sliding said distal portion about the mandrel disposed within an inner cavity, and the step of placing an inserter about said collapsed distal portion comprising turning at least one portion of the cap inside-out to retain said distal portion.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brandon Jackson whose telephone number is (571)272-3414. The examiner can normally be reached on Monday - Friday 8-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Bianco can be reached on (571)272-4940. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Brandon Jackson
Examiner
Art Unit 3772

BLJ

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4-16-07